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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,093

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Stefan Droschel

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EXAMINER

SCHIRO, RYAN RAYMOND

ART UNIT

PAPER NUMBER

1792

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,093	<b>Applicant(s)</b> DROSCHER ET AL.	
	<b>Examiner</b> RYAN SCHIRO	<b>Art Unit</b> 1792	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-14, 16, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's election of claims 1-10 and 15-18 in the reply filed on September 25, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election of the species of nicotinic acid amide as the photoinitiator compound of claims 9 and 17 has not been traversed. Claims 8, 10, 16 and 18 are drawn to a nonelected species. Claims 1-7, 9, 15 and 17 are pending and presented for examination.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Swan et al (US 2002/0004140 A1).

Claims are drawn to a method of immobilizing a polymer hydrogel on the surface of a polymer substrate, whereby a hydrogel layer containing at least one polymer and one non-toxic photoinitiator compound is present and the hydrogel layer is irradiated with electromagnetic radiation so that the hydrogel is immobilized on the surface of the polymer substrate.

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Swan discloses a method comprising forming a polymer layer on a support surface by the use of a coating agent and polymerizable compounds (abstract). Swan provides a method for using a coating agent to form a polymer layer on a support surface. The coating agent provides a first photoreactive group used to attach the coating agent to the substrate and a second photoreactive group used to initiate polymerization of the polymerizable groups on the support surface upon being contacted with electromagnetic radiation (0011-0020). The polymerizable groups taught by Swan include polyvinylpyrrolidinone and polyethylene glycol, which are admitted known hydrogel polymers in the Applicant's specification (0072, 0079). Also, Swan teaches immobilizing the coating agents by photoactivation on a variety of polymer substrates including polypropylene, polyvinyl chloride, polycarbonate, polyolefins and polyurethanes (0085). The support surface materials can be used to fabricate implant devices such as grafts, stents, catheters, dialysis tubing and many other biomedical devices (0087). Swan teaches that the photoinitiator species particularly preferred are thioxanthone, as required by claims 7 and 15, and its derivatives, having excitation energies greater than about 360 nm (0049). Swan teaches irradiating the photoinitiator species with electromagnetic radiation in the 330-340 nm wavelength range (0139).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al.

Swan teaches irradiating the photoinitiator species with electromagnetic radiation in the 330-340 nm wavelength range, as required by claim 2 (0139).

It is well settled that determination of optimum values of cause effective variables such as the wavelength range of electromagnetic radiation for the photoinitiator is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Swan does not teach nicotinic acid amide as the initiator compound, as required by claims 9 and 17.

Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan in view of Kondo et al (JP 54060386A)

Kondo teaches the use of nicotinamide derivatives as an initiator for photopolymerizable compounds (abstract). Also, Kondo teaches that the polymerisable compound has an

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ethylenically unsaturated double bond (abstract). Oligomers having at least one hydroxyl group within the molecule are specifically mentioned as preferred embodiments (abstract).

It would have been obvious to a person ordinarily skilled in the art at the time of the invention to combine the use of a nicotinamide initiator with the method of forming a polymer layer on a support surface taught by Swan. One would have been motivated to include the photoinitiator of Kondo because Kondo teaches that the nicotinic acid amide polymerizes ethylenically unsaturated double bonds, which are preferred monomers of Swan, at a faster rate and more efficiently than other photoinitiators.

### ***Response to Arguments***

Applicant's arguments with respect to claim 1-7 and 15 filed September 25, 2008 have been fully considered but they are not persuasive. Applicant claims that Swan only teaches forming a polymer on a substrate surface and not immobilizing a pre-formed polymer to a substrate. Swan teaches immobilizing the coating agents by photoactivation on a variety of polymer substrates including polypropylene, polyvinyl chloride, polycarbonate, polyolefins and polyurethanes (0085). In a preferred embodiment of Swan the method of immobilizing the polymer involves a two step process, involving sequential steps in which coating agent is first attached to the surface, after which compounds are polymerized thereon using the photoinitiator of the attached agent (0061). Also, Swan teaches that the two steps of attaching and polymerizing can be performed simultaneously (0061). In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner and result, was held to not patentably distinguish the processes, *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959).

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Applicant's arguments with respect to claims 9 and 17 have been fully considered and are not persuasive. The general formula of the photoinitiator, 1-(substituted or unsubstituted) benzyl-1,4-dihydronicotinamide, taught by Kondo is shown in the General Formula I in claim 1. The unsubstituted form of the General Formula 1 is nicotinic acid amide, as required by claims 9 and 17.

### Conclusion

Claims 1-7, 9, 15 and 17 are rejected.

Applicant's amendment necessitated the new grounds of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Schiro whose telephone number is 571-270-5345. The examiner can normally be reached on Monday-Friday, with every other Friday off, from 8:30 AM to 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on (571) 270-1414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ryan Schiro  
Art unit 1792

/Michael Barr/

Supervisory Patent Examiner, Art Unit 1792